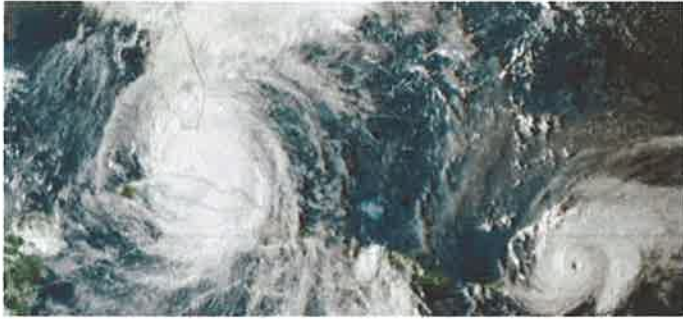




Current Drug Shortages

- Emergency syringes
 - Expiration dating extended
 - Temporary import of sodium bicarbonate injection
 - Expediting review of additional manufacturers
 - Fresenius Kabi returned their sodium bicarbonate injection in vials to market
 - Sodium glycerophosphate is being temporarily imported by Fresenius Kabi



Hurricane Maria



- Products affected include dextrose, saline, sterile water for injection, and amino acids
- Temporary import from Baxter facilities in Ireland, Australia, Mexico, and Canada and B. Braun in Germany
- Expedited review of applications for new suppliers

PROTECT YOUR PATIENTS

Know your responsibilities under the Drug Supply Chain Security Act

The Drug Supply Chain Security Act (DSCSA) includes requirements that pharmacies must follow to protect patients from receiving harmful drugs, such as counterfeit or other illegitimate drugs.

The DSCSA was enacted in 2013 to further secure our nation's drug supply. It creates a tighter, closed prescription drug distribution system to **prevent** harmful drugs from entering the supply chain, **detect** harmful drugs if they do enter the supply chain, and enable **rapid response** when such drugs are found.

By law, pharmacies are **required** to:



Confirm the entities you do business with are licensed or registered

To help determine whether trading partners who you do business with (manufacturing, repackagers, wholesale distributors, third-party logistics providers, and pharmacies) are licensed or registered:



Receive, store, and provide product tracing documentation

The law requires drugs to be traced as they move through the supply chain, and pharmacies must:



Investigate and properly handle suspect and illegitimate drugs

Pharmacies must have a process to investigate and handle suspect and illegitimate prescription drugs, which includes drugs that may be or have evidence that it is counterfeit, diverted, stolen, intentionally adulterated, or unfit for distribution, including steps to:

The Opioid Crisis: FDA's Priorities & Strategies

FDA

1. Decreasing Exposure & Prevent New Addiction



Appropriate Dose/Duration Labeling



Appropriate Packaging, Storage, and Disposal



Health Care Provider Education

2. Supporting the Treatment of Those With Opioid Use Disorder



Naloxone



Medication Assisted Treatment (MAT)

3. Fostering the Development of Novel Pain Treatment Therapies



Partnerships & Meetings



Abuse Deterrent Formulations (ADFs)



Pain Treatment Alternatives

4. Improving Enforcement & Assessing Benefit-Risk



Improving Enforcement



Assessing Benefit-Risk